

## **Remarks/Arguments**

### **A. Amendment to Comply With Requirements for Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures**

In order to Comply with Requirements for Patent Applications Containing Nucleotide Sequence and/or Amino Acid sequence Disclosures, SEQ ID NOs. have been added in the description, more particularly in the Brief Description of the Drawings on page 27 and at pages 52 to 54 of the Description, in accordance with a new Sequence Listing filed herewith.

The previous Sequence Listing submission included a duplication of SEQ ID NOs: 308 and 309. With the instant submission, this duplication is corrected and SEQ ID NO:309 is a mutation of SCN 1A shown in Figure 3 (ATC ATA TAC TTC CTG) which was inadvertently omitted from the Sequence Listing as filed.

No new matter has been entered by the foregoing amendments.

### **B. Applicant's Election With Traverse**

In response to the Restriction Requirement, Applicant elects SEQ ID NO:65 (Adult SCN3A in claims 14-22) with traverse.<sup>1</sup>

The Examiner fails to establish that a search of the complete application would be an undue burden. MPEP § 803 (“[i]f the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions”). All claimed sequences relate to the same gene, *i.e.*, SCN3A, and therefore share several functional and structural features (see

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<sup>1</sup> Applicant's arguments against the Restriction Requirement are based on the: (1) lack of an additional burden—much less a “serious burden”—to search all of the claimed sequences; and (2) new policy set forth by the U.S. Patent Office. Such arguments do not create an estoppel against Applicants and are not an admission that the restricted Groups are either patentably distinct or patentably indistinct from one another. This applies to all of Applicant's arguments against all of the Restrictions.

application). Because of these functionally and structurally similar features, there is no “serious burden” to search all of the claimed sequences.

Further, the Restriction Requirement is contrary to the U.S. Patent Office’s policy in examining nucleic acid sequences. It divides the claims into several groups, thereby placing an inordinate economic burden on Applicant to obtain a reasonable scope of patent protection for the invention. The U.S. Patent Office has recognized this burden and has implemented a new policy with respect to Restriction Requirement practice for nucleic acid sequences:

In establishing the new policy, the Commissioner has partially waived the requirements of 37 C.F.R. 1.141 and will permit a reasonable number of such nucleotide sequences to be claimed in a single application. Under this policy, **in most cases, up to 10 independent and distinct nucleotide sequences will be examined in a single application without restriction.** Those sequences which are patentably indistinct from the sequences selected by applicant will also be examined. Nucleotide sequences encoding the same protein are not considered to be independent and distinct and will continue to be examined together. In some exceptional cases, the complex nature of the claimed material may necessitate that the reasonable number of sequences to be selected be less than 10. In other cases, applicants may petition pursuant to 37 CFR 1.181 for examination of additional nucleotide sequences by providing evidence that the different nucleotide sequences do not cover independent and distinct inventions.

MPEP § 2434 (emphasis added); see also *id.* at § 803.04 (recognizing the economic burden “[n]evertheless, to further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the Director has decided *sua sponte* to partially waive the requirements of 37 CFR 1.141 *et seq.* and permit a reasonable number of such nucleotide sequences to be claimed in a single application...It has been determined that normally ten sequences constitutes a reasonable number for examination purposes. Accordingly, in most cases, **up to ten independent and distinct nucleotide sequences will be examined in a single application without restriction....**”) (emphasis added). Therefore, Applicant is entitled to have at least 10 additional sequences searched and requests that such a search be performed prior to issuance of the next office action.

Applicant reserves all rights in the non-elected inventions, including the right to file one or more divisional applications covering the subject matter thereof.

**C. Conclusion**

Applicant believes that this is a full and complete response to the Restriction Requirement mailed March 2, 2006. Applicant requests that the Restriction Requirement be withdrawn and that all claims be examined for the their full scope.

**Petition for a Two-Month Extension of Time**

Pursuant to 37 C.F.R. § 1.136(a), Applicant petitions for a two-month extension of time to and including June 2, 2006, in which to respond to the Restriction Requirement mailed March 2, 2006. Pursuant to 37 C.F.R. § 1.17, a check in the amount of \$225.00 is enclosed, which is the process fee for a two-month extension of time for a small entity status. If the check is inadvertently omitted, or should any additional fees under 37 C.F.R. §§ 1.16 to 1.21 be required for any reason relating to the enclosed materials, or should an overpayment be included herein, the Commissioner is authorized to deduct or credit said fees from or to Fulbright & Jaworski Deposit Account No. 50-1212/GOUD:023USD3.

Should the Examiner have any questions, comments, or suggestions relating to this case, the Examiner is invited to contact the undersigned Applicants' representative at (512) 536-3020.

Respectfully submitted,



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